DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 23, 2015

NeuroWave Systems Inc.
Tatjana Zikov
President
2490 Lee Blvd., Suite 300
Cleveland Heights, OH 44118

Re: K142834
Trade/Device Name: DiscoverEEG System, Model DE-401
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMC
Dated: May 10, 2015
Received: May 11, 2015

Dear Tatjana Zikov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142834

Device Name
DiscoverEEG System, DE-401

Indications for Use *(Describe)*
The DiscoverEEG System, Model DE-401 is intended to be used for measuring and recording the electrical activity of a subject's brain, obtained by placing non-invasive electrodes on the head. The DiscoverEEG, DE-401 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and at home and for clinical research. The medical use of data acquired by the DiscoverEEG is to be performed under the direction and interpretation of a licensed medical professional. The DiscoverEEG, Model DE-401 does not provide any diagnostic conclusion about the subject's condition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) SUMMARY

1. Contact Details

Applicant Name: NeuroWave Systems Inc.
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(216) 361-1591 (telephone)
(216) 361-1554 (fax)

Contact: Tatjana Zikov,
President
tzikov@neurowavesystems.com

Date Prepared: September 29, 2014

2. Device Name

Trade Name:	DiscoverEEG System, Model DE-401
Common/Usual Name:	EEG Monitor
Classification Name:	Electroencephalograph
Product Code:	OMC
Regulation Number:	21 CFR 882.1400
Device Class:	Class II
Classification Panel:	Neurology

3. Legally Marketed Predicate Device

510(k) Number	Product Code	Trade Name	Manufacturer
K092477	OMC	NeuroFAST Monitoring System, Model NF-201	NeuroWave Systems, Inc.
K101830	OLV, OMC	Zmachine	Consolidated Research of Richmond, Inc.

4. Description of Device

The DiscoverEEG System, Model DE-401, is a wearable, medical-grade EEG device that acquires and stores up to four electroencephalograms (EEGs) obtained from non-invasive electrodes placed on a subject's head. The acquired EEG waveforms, as well as, processed EEG spectral variables are continuously stored by the system for later retrieval. The data can be transferred from the DiscoverEEG hardware to a computer for review.

The DiscoverEEG System, Model DE-401 has four main components:

- Acquisition Module: contains the circuitry for acquisition of the EEG signals through connections to the electrodes placed on the subject's head. The acquired signals are digitized and then passed to the Memory Module, for signal processing and storage.
- Memory Module: provides power to the system and contains memory and EEG processing circuitry (impedance check, lead off check, pre-processing incl. artifact removal, processed spectral variables). Includes LED indicators for assurance of proper operation and other user interface elements. May contain a wireless option for data transfer to Data Viewer Software in real-time.
- Disposable Electrode Array: contains noninvasive, disposable, single patient electrodes (5 electrodes, 4 EEG channels) and skin preparation materials. The packaging will guide the user on how to prepare the subject's skin and how to place the electrodes.
- Data Viewer Software: PC based software used for retrieving and reviewing acquired raw EEG waveforms (as well as processed data) from the DiscoverEEG hardware. This software will also be capable of converting the retrieved EEG data files to standard formats (i.e. EDF+, tab-delimited). Such converted data files can then be reviewed using off-the-shelf bio-signal review software that accepts the converted format.

5. Intended Use

The intended use of DiscoverEEG System, Model DE-401 is consistent with the classification 21 CFR 882.1400, Electroencephalograph:

> "An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head."

The DiscoverEEG System, Model DE-401 is intended to be used for measuring and recording the electrical activity of a subject's brain, obtained by placing non-invasive electrodes on the head. The DiscoverEEG, DE-401 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and at home and for clinical research. The medical use of data acquired by the DiscoverEEG is to be performed under the direction and interpretation of a licensed medical professional. The DiscoverEEG, Model DE-401 does not provide any diagnostic conclusion about the subject's condition.

6. Substantial Equivalence Comparison

The technology of the DiscoverEEG DE-401 device is equivalent to other EEG monitor devices. The EEG signal is acquired in analog format, digitized, processed and saved for later user interpretation. An Electrode (Sensor) Array is provided with the system for the convenience of the user in applying the acquisition electrodes. The Electrode Array is made of the materials that have been shown to pass cytotoxicity, primary skin irritation and sensitization as required (refer to section 15 for addition details).

Feature	DiscoverEEG System, Model DE-401	NeuroFAST Monitoring System, Model NF-201 (092477)	Zmachine (101830)
Indications for Use	The DiscoverEEG System, Model DE-401 is intended to be used for measuring and recording the electrical activity of a subject's brain, obtained by placing non-invasive electrodes on the head. The DiscoverEEG, DE-401 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and at home and for clinical research. The medical use of data acquired by the DiscoverEEG is to be performed under the direction and interpretation of a licensed medical professional. The DiscoverEEG, Model DE-401 does not provide any diagnostic conclusion about the subject's condition.	The NeuroFAST Monitor NF-201 is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the head. The NeuroFAST NF-201 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and for clinical research. The NeuroFAST Monitor is to be used under the direction and interpretation of a licensed medical professional. The NeuroFAST Monitor NF-201 does not provide any diagnostic conclusion about the patient's condition.	The CR1 Zrnachine is a single-channel EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.
Modalities	EEG	EEG	EEG
Environment of Use	Operating room, intensive care unit, emergency room, clinical settings and At Home where EEG monitoring is used.	Operating room, intensive care unit, emergency room, and clinical settings where EEG monitoring is used.	In the home or clinical environment
Power Source	Battery	120 Volt 60Hz AC power	Li Ion Battery
System Components	Electrode (Sensor) Array, Acquisition and Memory Modules, Data Viewer Software	Patient Module, Patient Cable, Display Module, Data Cable and EasyPrep Electrode Kit	Zmachine device, EEG sensors, Sensor cable, wall charger
Sensing Electrodes	Silver-silver chloride disposable EEG electrodes	Silver-silver chloride disposable EEG electrodes	Silver-silver chloride disposable electrodes

Feature	DiscoverEEG System, Model DE-401	NeuroFAST Monitoring System, Model NF-201 (092477)	Zmachine (101830)
Screen Display Details	Data Viewer Software: 1) Raw EEG Waveforms 2) Signal Quality information: Channel Connection flags, Impedance values, Artifact Detection flags, Noise Level 3) Spectral Parameters: EEG power spectrum and frequency bands, 50% 50% Median Edge Frequency (MEF), and 95% Spectral Edge Frequency (SEF)	Displays: 1) Raw EEG Waveforms 2) Signal Quality information: Channel Connection flags, Impedance values, Artifact Detection flags, Noise Level 3) Spectral Parameters: EEG power spectrum and frequency bands, 50% 50% Median Edge Frequency (MEF), and 95% Spectral Edge Frequency (SEF)	Displays: Sleep/Wake Statistics
Stored EEG data available	Yes – SD Card	Yes – through removable storage	Yes - microSD
EEG Channels/ Montage	Up to 4 channels (2 fronto-temporal channels, and 2 temporal channels)	2 bilateral fronto-temporal channels viewed concurrently	1 channel, differential mastoid
Real Time EEG Display	Yes, if wireless option is present	Yes	No
Processed EEG Bandwidth	User Selectable in Data Viewer software Low Filter: 0.125 or 0.5 Hz High Filter: 30 or 70 Hz	User Selectable Low Filter: 0.125 or 0.5 Hz High Filter: 30 or 70 Hz	0.5-380 Hz
Automatic Artifacting	Yes	Yes	Unknown
Amplifier Common Mode Rejection Ration (CMRR)	≥110 dB	≥100 dB	Unknown
Amplifier Input Impedance	≥100 Meg Ohm	≥50 Meg Ohm	10 Gig Ohms
Electrode Impedance Test	Yes	Yes Continuous and on demand by the user	Yes

Feature	DiscoverEEG System, Model DE-401	NeuroFAST Monitoring System, Model NF-201 (092477)	Zmachine (101830)
Derived / Processed EEG Measures	Power spectrum parameters derived from FFT: 1) Power spectrum displayed as Density Spectral Array (DSA) 2) 95% Spectral Edge Frequency (SEF) 3) Median Edge Frequency (MEF) 4) Spectral Powers in EEG frequency bands traditionally used to quantify EEG signals (α, β1, β2, δ, θ and γ) Signal Quality information (Channel connection flags, Impedance values, Artifact Detection flags, Noise Level)	Power spectrum parameters derived from FFT: 1) Power spectrum displayed as Density Spectral Array (DSA) 2) 95% Spectral Edge Frequency (SEF) 3) Median Edge Frequency (MEF) 4) Spectral Powers in EEG frequency bands traditionally used to quantify EEG signals (α, β1, β2, δ, θ and γ) Signal Quality information (Channel connection flags, Impedance values, Artifact Detection flags, Noise Level)	Wake/Sleep Determination
Contains patient isolation	Battery powered, thus no connection between patient and mains	Yes – Patient module (analog-to digital converter) provides 6kV electrical isolation of the patient from the monitor	Battery powered, thus no connection between patient and mains
Display Interface	Yes, LEDs to ensure proper system connection and operation.	Yes – High-resolution, color, graphical user interface and touch screen	Yes, To ensure proper system connection and operation.
Event Markers	Yes, artifact detection and signal quality events User selectable events included in Data Viewer software	Yes, user selectable	Yes, Sleep/Wake Events

7. Non-clinical Testing

Laboratory testing, performed on identical hardware to the DiscoverEEG subject of this submission, demonstrated that the DiscoverEEG, Model DE-401 meets its design and functional requirements. Actual device functions and features were evaluated against the device specifications and in all instances the DiscoverEEG, Model DE-401 performed as expected and no unexpected behavior was observed.

Prior to commercial introduction, the device will meet the requirements of UL medical electrical equipment standards for safety and the IEC particular standard for electroencephalographs.

To ensure safety, the DiscoverEEG, Model DE-401 will comply with all applicable requirements of IEC60601-1 and IEC60601-1-11, and will also comply with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

To ensure electromagnetic compatibility, the DiscoverEEG, Model DE-401 will comply with all applicable requirements of IEC60601-1-2, and will also comply with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

8. Clinical Testing

The DiscoverEEG, Model DE-401 device is an electroencephalographic device comprised of hardware that has been bench tested to assess safety and effectiveness and to establish substantial equivalence with the predicate devices. We believe further clinical data is not required to demonstrate performance for the DiscoverEEG, Model DE-401 for the indication for use subject to this submission.

9. Conclusion

The DiscoverEEG, Model DE-401, when compared to its predicate devices, has the similar intended use and technological characteristics and principles of operation. The nonclinical tests demonstrate that the device is safe, as effective, and performs at least as safely and effectively as the legally marketed devices. Thus, in indications, intended use and technology, the DiscoverEEG, Model DE-401 is substantially equivalent to the predicated devices. Minor technological difference as documented in the Substantial Equivalence Comparison table above, raise no new questions of safety or effectiveness.